REMARKS

Claims 5-9, 11, 14, 15, 18, 25, 37-40, and 43-47 are pending in the application. The maintained and newly made rejections and objections are addressed as follows.

Maintained Rejections

Rejections under 35 U.S.C. § 102(b)

Claims 5, 6, 14, 15, and 18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by WO 96/31235, in light of the English version of this document, U.S. Patent No. 6,126,938. This rejection appears to be maintained in part on the basis that the rejected claims encompass mucosal administration, which Applicants respectfully submit is not the case. The claims specify that the mode of administration is by the subdiaphragmatic, systemic route. The systemic route does not include mucosal routes. This is made clear by references throughout the specification of the systemic route as "the systemic or parenteral route," which shows that these terms are considered as interchangeable. On page 20, it is stated that "a preferred method by which a protective effect is obtained is in particular a method according to which the immunogenic agent is administered exclusively by the systemic or parenteral route (strict systemic route)" and that "a method in which the immunogenic agent is administered by the systemic route and by the mucosal route does not correspond to the definition above." By referring to these routes (systemic and mucosal) as separate in this manner, it is clear that they are intended to be different routes. In the interest of expediting prosecution, claim 5 has been amended to specify the strict systemic route, and claim 14 has been canceled.

The Examiner has also stated in this rejection that the claims require stimulation of a

systemic immune response, and indicates that this may be obtained by mucosal administration, which is thus covered by the rejected claims. Applicants respectfully disagree with this characterization. The present claims require administration by a systemic route, which delineates the manner by which administration actually takes place, and not necessarily the type of immune response induced. As discussed above, mucosal administration is not included within what is taught in the application as systemic administration, which is made clear to be equivalent to parenteral administration. In view of the above, Applicants respectfully submit that any reference in WO 96/31235 to mucosal administration is not relevant to the rejected claims.

With respect to the teachings of dorsolumbar administration in WO 96/31235 to which the Examiner refers, Applicants note that the dorsolumbar route is taught in WO 96/31235 for use in combination with mucosal administration.

The present claims specify a method that "consists essentially of" subdiaphragmatic, systemic administration, which excludes the type of administration taught in WO 96/31235. In particular, Applicants submit that the addition of different routes of administration would be considered as changing the basic characteristics of the claimed method, as the addition of such different routes could result in a very different immune response (in both quality and quantity). This is supported by the fact that WO 96/31235 (U.S. Patent No. 6,126,938) emphasizes the benefits of combining mucosal and dorsolumbar routes. For example, U.S. Patent No. 6,126,938 states, in highlighting that multiple routes of immunization are a basic feature of the '938 patent, that: "It has now been found that an immune response at a mucosal site of any kind and against an antigen of any kind could be greatly promoted by implementing an immunization protocol combining several routes" (column 3, lines 64-67). Thus, Applicants submit that the teachings of

WO 96/31235 are outside of the scope of the present claims, and this rejection can therefore now be withdrawn.

Claim 5 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Fulginiti et al., in light of Chen et al. (1993), and Meyer et al. (EP 0835928). This rejection is based in part on the teaching in Fulginiti of intragastric administration. As noted above, mucosal administration is not included in the scope of the claim 5, so intragastric administration is not relevant. This rejection is also based on Fulginiti's teaching of intraperitoneal administration, and the position that this teaching inherently discloses the present invention. In response, Applicants note that claim 5 has been amended to specify administration to a primate, and new claim 48 has been added to specify that the primate is a human. As the intraperitoneal administration of Fulginiti was carried out in a mouse (and not a primate), this rejection should be withdrawn.

Rejection under 35 U.S.C. § 102(e)

Claims 5 and 6 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Michetti et al., U.S. Patent No. 6,290,962, in light of Guy (1997), on the basis that rectal administration is subdiaphragmatic and that the type of immune response induced is both systemic and mucosal. The Examiner refers to page 19, line 27 as supporting that rectal administration is included in the present invention.

Applicants respectfully request reconsideration of this rejection. As discussed above, the claims 5 (and dependent claim 6) specify systemic, and not mucosal administration. The passage on page 19, line 27 to which the Examiner refers concerns a method that is different from the systemic administration method of the present claims. In particular, in addition to the

subdiaphragmatic systemic administration method of claim 5, the invention also includes a separate method, involving mucosal administration followed by parenteral administration. This method is encompassed within claim 25, and is not relevant to claim 5. Further, even if systemic antibodies are induced by Michetti's method, this does not mean that the approach used in Michetti was systemic. Rather, the approach used by Michetti was a mucosal approach and, therefore, Applicants respectfully request that this rejection be withdrawn.

Double Patenting Rejections

Claims 5-9, 14, and 15 stand rejected for obviousness-type double patenting over claims 1-28 of U.S. Patent No. 6,126,938. Applicants request reconsideration of this rejection for the reasons discussed above in reference to the rejection for anticipation over WO 96/31235. In particular, the rejected claims specify a method consisting essentially of subdiaphragmatic, strict systemic administration, and exclude mucosal administration, and the claims of U.S. Patent No. 6,126,938, which corresponds to WO 96/31235, require mucosal administration. This rejection should therefore be withdrawn.

Claims 5-8 and 18 stand rejected for obviousness-type double patenting over claims 1-14 of U.S. Patent No. 6,576,244. In response, Applicants note that '244 patent requires administration by injection of an *H. pylori* polypeptide and a particular adjuvant (i.e., an adjuvant comprising the heat-labile toxin of *E. coli*, the B subunit thereof, cholera toxin, or the B subunit thereof). These claims make no mention of administration by the subdiaphragmatic, strict systemic route, as required by the rejected claims. In addition, the rejected claims do not require use of the adjuvants listed in the claims of the '244 patent. In view of these differences,

Applicants request that this rejection be withdrawn.

Claim 5 stands rejected for obviousness-type double patenting over claims 1, 13, 15, and 18 of U.S. Patent No. 6,379,675. In response, Applicants note that the '675 patent requires the administration of Osp antigens, which are *B. burgdorferi* lipoproteins, in contrast to the *H. pylori* polypeptide antigen of claim 5. The '675 claims also require the enhancement of an immunological response to an OspC antigen. Even if the administration of Helicobacter antigens may also be covered, this does not change the fact that the methods are focused on Osp antigens. The present claims do not cover enhancement of an immunological response to an OspC antigen. In view of these differences, Applicants request that this rejection be withdrawn.

New Rejections and Objections

Objections under 37 C.F.R. § 1.75(c)

Claims 14, 15, 18, 39, 45, and 46 were objected to under 37 C.F.R. § 1.75(c) for being in improper dependent form. The Examiner states that claims 14, 15, 18, 45, and 46 specify any immunogenic agent, which is broader in scope than the species of polypeptide antigen of claims 5 and 25, from which the rejected claims depend. Applicants respectfully disagree with this rejection, as the dependent claims each specify administration of "the *Helicobacter pylori* antigen" (emphasis added), which is clearly referring to the same Helicobacter antigen as specified in the claims from which the rejected claims depend. This notwithstanding, in the interest of expediting prosecution, Applicants have amended the dependent claims to specify "said *Helicobacter pylori* polypeptide antigen" in the same manner as in the independent claims. Claim 39 was objected to for being of the same scope as the claim from it depends. Claim 39

has been canceled herein, without prejudice. In view of the above, Applicants request that the objections be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 7 was rejected under 35 U.S.C. § 112, second paragraph for lack of antecedent basis for induction of a TH2-type immune response. Claim 7 has been amended to specify that the method further comprises induction of a TH2-type response and, thus, Applicants submit that this rejection may be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 5-9, 14, 15, 18, 25, 37-40, and 45-47 were rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. The Examiner states that the specification enables induction of an immune response against *Helicobacter pylori*, as well as induction of an immune response for reducing the degree of infection, but not preventing or treating infection. In the interest of expediting prosecution, claims 5 and 25, from which the remaining claims depend, have been amended to specify that which the Examiner has deemed enabled (induction of an immune response against *Helicobacter pylori*, and induction of an immune response for reducing the degree of infection). References to prevention and treatment have been removed from the claims. For the record, Applicants note that they disagree with this rejection and submit that the amendment does not change the scope of the claims. For example, those of skill in the art would certainly consider a reduction of degree of infection as treatment of the infection. This notwithstanding, in view of the amendments, Applicants request that this rejection be withdrawn.

Rejection under 35 U.S.C. § 102(b)

Claims 25, 37-40, and 45-47 were rejected under 35 U.S.C. § 102(b) as being anticipated by Thomas et al., WO 97/02835. Applicants respectfully request reconsideration of this rejection, in view of the present amendment. In particular, claim 25 has been amended to specify that the administered antigen is a *Helicobacter pylori* polypeptide comprising the UreB or UreA subunit of a *Helicobacter pylori* urease, and such polypeptides are not taught in WO 97/02835. This rejection may therefore be withdrawn.

CONCLUSION

Enclosed is a Petition to extend the period for replying to the Office action for 3 months, to and including September 18, 2008, and authorization to charge $1,050.00 to Deposit Account No. 03-2095. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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